CHLO TUSS- chlophedianol hydrochloride, dexbrompheniramine maleate, pseudoephedrine hydrochloride liquid R.A. McNeil Company

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Chlo Tuss

Drug Facts

Active ingredients

(in each 5 mL teaspoonful)

Chlophedianol Hydrochloride 12.5 mg

Dexbrompheniramine Maleate 1 mg

Pseudoephedrine Hydrochloride 30 mg

Purpose

Cough Suppressant

Antihistamine

Nasal Decongestant

Uses

temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- cough due to minor throat and bronchial irritation
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- nasal congestion
- reduces swelling of nasal passages

Warnings

Do not exceed recommended dosage.

Do not use this product

• if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease),

or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have

- a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- a cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland
- heart disease
- high blood pressure
- thyroid disease
- diabetes

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- excitability may occur, especially in children
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash or persistent headache. A persistent cough may be a sign of a serious condition.
- new symptoms occur

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Do not exceed recommended dosage.

	2 teaspoonfuls (10
	mL)
Adults and children	every 6 hours, not
12 years of age and	to

exceed 8 over:

> teaspoonfuls in 24 hours

1 teaspoonful (5 mL) every 6 hours, not

Children 6 to under

to 12 years of age: exceed 4

> teaspoonfuls in 24 hours

Children under 6 years of age:

Consult a doctor

Other information

Store at 59° - 86°F (15° - 30°C)

Inactive ingredients

Citric Acid, Glycerin, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol. Tutti Frutti Flavor.

Questions? Comments?

Serious side effects associated with use of this product may be reported to this number. Call 1-423-493-9170 (8 a.m. to 5 p.m.)

PRODUCT PACKAGING

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

Dispense in a tight, light-resistant container with a child-resistant cap.

THIS BOTTLE IS NOT TO BE DISPENSED TO THE CONSUMER.

Manufactured by: Woodfield Pharmaceutical, LLC Houston, TX 77099

Manufactured for: R.A. McNeil Company 1150 Latta Street Chattanooga, TN 37406-3738

Patent Pending

Rev. 06/15



NDC 12830-762-16

Chlo Tuss

(Reformulated)



- Cough Suppressant
- Antihistamine
- Nasal Decongestant

Tutti Frutti Flavor

EACH 5 mL (1 TEASPOONFUL) CONTAINS:

Chlophedianol Hydrochloride 12.5 mg Dexbrompheniramine Maleate 1 mg Pseudoephedrine Hydrochloride 30 mg

Alcohol Free/Gluten Free Sugar Free/Dye Free

ONE PINT (473 mL)

Mfg. for R.A. McNeil Company Chattanooga, TN 37406-3738

Rev. 06/15

Drug Facts Lift Here

Active ingredients Pur (in each 5 mL teaspoonful) Purpose

Chiophedianol Hydrochloride 12.5 mg.. Cough Suppressant Dexbrompheniramine

Maleate 1 mg..... Antihistamine

Pseudoenhedrine

Hydrochloride 30 mg Nasai Decongestant

Uses temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies: • cough due to minor throat and bronchial

- Irritation
- runny nosa
- ■sneezing
- itching of the nose or throat
- Itchy, watery eyes
- nasal congestion
- reduces swelling of nasal passages

Warnings

Do not exceed recommended dosage.

Do not use this product

 If you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAÓI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema

Drug Facts (continued)

- ■a cough that occurs with too much phiegm (mucus)
- a breathing problem such as emphysema or chronic bronchitts
- glaucoma
- ■trouble urinating due to an enlarged prostate gland
- heart disease ■ high blood pressure
- ■thyroid disease
- diabetes

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product

- excitability may occur, especially in children
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may Increase the drowsiness effect
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor If

- nervousness, dizziness, or sleeplessness occur cough or nasal congestion persists for more than 1 week, tends to recur, or is
- accompanied by a fever, rash or persistent headache. A persistent cough may be a sign of a serious condition.
- new symptoms occur

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions

Do not exceed recommended dosage.

Adults and children 12 years of age and over:

2 teaspoonfuls (10 mL) every 6 hours, not to exceed 8 teaspoonfuls In 24 hours

Children 6 to of age:

1 teaspoonful (5 mL) under 12 years every 6 hours, not to exceed 4 teaspoonfuls In 24 hours

Children under Consult a doctor

6 years of age:

Other information

Store at 59° - 86° F (15° - 30° C)

Inactive ingredients

Citric Acid, Glyčerin, Propylene Glycol, Purtfled Water, Sodium Citrate, Sodium Saccharin, Sorbitol, Tutti Frutti Flavor.

Questions? Comments?

Serious side effects associated with use of this product may be reported to this number, Call 1-423-493-9170 (8 a.m. to 5 p.m.)

CHLO TUSS

chlophedianol hydrochloride, dexbrompheniramine maleate, pseudoephedrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12830-762
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CHLOPHEDIANOL HYDROCHLORIDE (UNII: 69QQ58998Y) (CHLOPHEDIANOL - UNII:42C50P12AP)	CHLOPHEDIANOL HYDROCHLORIDE	12.5 mg in 5 mL
DEXBROMPHENIRAMINE MALEATE (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP)	DEXBROMPHENIRAMINE MALEATE	1 mg in 5 mL
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg in 5 mL

Inactive Ingredients			
Ingredient Name	Strength		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SORBITOL (UNII: 506T60A25R)			

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	TUTTI FRUTTI	Imprint Code	
Contains			

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12830-762- 16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2013	
2	NDC:12830-762- 15	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/09/2015	

Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date

OTC monograph final	part341	10/01/2013	

Labeler - R.A. McNeil Company (008305220)

Revised: 11/2021 R.A. McNeil Company